
EXHIBIT 8A

Document Chronology/Due Diligence Logs for IND No. 47,838

Regulatory Affairs

JLP41868
30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)
Date Range: All
Date Communication Type Document Type Document Subtype Serial / Supp #

CARDS
Chronology

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12:16:18

22-Aug-1994 Food and Drug Administration Correspondence Export Authorization

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Export: Authorization

26-Jan-1995 Food and Drug Administration Correspondence Export Authorization

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Export: Authorization

03-Feb-1995 GlaxoSmithKline FAX/E-mail Export

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Export

23-Feb-1995 Food and Drug Administration Correspondence Export Authorization

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Export: Authorization

28-Feb-1995 GlaxoSmithKline Correspondence General Correspondence

Pre-IND GI198745 (5-alpha reductase inhibitor)
General Correspondence: Request for Comment

Regulatory Affairs

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JLP41868
30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
24-Apr-1995	GlaxoSmithKline Correspondence	Initial Investigational New Drug Application	CMC Protocol(s) Included Study Reports	0000
		Protocol Amendment: New Protocol Protocol Amendment: New Investigator	Investigator Add	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Initial Investigational New Drug Application: CMC, Protocol(s) Included, Study Reports Protocol Amendment: New Protocol Protocol Amendment: New Investigator Serial No.: 0000			
28-Apr-1995	Food and Drug Administration Correspondence	Acknowledgement	IND # Assigned	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Acknowledgement: IND # Assigned			
09-May-1995	GlaxoSmithKline Correspondence	General Correspondence	Clinical Nonclinical	0001
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 001			

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JLP41868
30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
23-May-1995	"	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Report of Selected Adverse Events Serial No.: 0002	General Correspondence	Report of Selected Adverse Events	0002
26-May-1995		GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) Record of Telecon	General Teleconference		
26-May-1995		Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) FDA Comment	Comment/Information Request		
05-Jun-1995		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Report of Selected Adverse Events Serial No.: 0003	General Correspondence	Report of Selected Adverse Events	0003
13-Jun-1995		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 004	General Correspondence	Clinical	0004

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JLP41868
30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
All				
13-Sep-1995	GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol Protocol Amendment: New Investigator	Investigator Add Investigator Add	0005
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Protocol Amendment: New Investigator Serial No.: 0005			
26-Sep-1995	GlaxoSmithKline Correspondence	Information Amendment: Chemistry Manufacturing and Controls	CMC	0006
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Chemistry Manufacturing and Controls Serial No.: 0006			
10-Oct-1995	GlaxoSmithKline Correspondence	Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Clinical Other 1572 Change	0007
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Serial No.: 007			
13-Oct-1995	GlaxoSmithKline Telephone Conversation	General Teleconference	Nonclinical	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Record of Telecon			

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30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)
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Date Range: All
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16-Oct-1995 GlaxoSmithKline Telephone Conversation General Teleconference Clinical

IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Teleconference: Clinical

18-Oct-1995 Food and Drug Administration Correspondence Comment/Information Request CMC

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Comment/Information Request: CMC

18-Oct-1995 Food and Drug Administration Correspondence Minutes of Meeting FDA Conference

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Minutes of Meeting: FDA Conference

25-Oct-1995 GlaxoSmithKline Correspondence General Correspondence 0008

IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence
Serial No.: 008

03-Nov-1995 GlaxoSmithKline Correspondence General Correspondence Clinical 0009

IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence: Clinical
Serial No.: 0009

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JLP41868
30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)
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Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
08-Nov-1995		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 010	Protocol Amendment: New Investigator	Investigator Add	0010
13-Nov-1995		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: CMC Serial No.: 0011	General Correspondence	CMC	0011
13-Dec-1995		GlaxoSmithKline Trip Report IND 47,838; GI198745 (5-alpha reductase inhibitor) Record of Visit to FDA	Trip Report		
29-Jan-1996		GlaxoSmithKline Correspondence	Information Amendment: Chemistry Manufacturing and Controls Information Amendment: Clinical Information Amendment: Nonclinical Protocol Amendment: New Protocol Protocol Amendment: New Investigator Protocol Amendment: Change in Protocol	CMC Nonclinical Investigator Add Clinical	0012

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JLP41868
30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date	Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Information Amendment: Chemistry Manufacturing and Controls
Information Amendment: Clinical
Information Amendment: Nonclinical
Protocol Amendment: New Protocol
Protocol Amendment: New Investigator
Protocol Amendment: Change in Protocol
Serial No.: 0012

29-Jan-1996		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 0013	General Correspondence	Clinical	0013
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08-Feb-1996		Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) FDA Comment	Comment/Information Request	Clinical Nonclinical	
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09-Feb-1996		GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Clinical	General Teleconference	Clinical	
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Regulatory Affairs

CARDS Chronology

JLP41868
30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)
12:16:18

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
12-Feb-1996	Food and Drug Administration Telephone Conversation	Comment/Information Request	Clinical Efficacy	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Clinical			
22-Feb-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 014	Protocol Amendment: New Investigator	Investigator Add	0014
22-Feb-1996	GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Electronic Submission	General Teleconference	Other	
29-Feb-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Nonclinical Serial No.: 015	Information Amendment: Nonclinical	Nonclinical Study Reports	0015
18-Mar-1996	GlaxoSmithKline Correspondence	General Correspondence	Clinical	0016

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JLP41868
30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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"IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence: Clinical
Serial No.: 0016

22-Mar-1996	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0017
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0017

02-Apr-1996	Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Nonclinical	Comment/Information Request	Nonclinical	
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15-Apr-1996	GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comment: Nonclinical	Response to FDA Request/Comment	Clinical Nonclinical	
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19-Apr-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Nonclinical Serial No.: 0018	General Correspondence	Nonclinical	0018
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Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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23-Apr-1996	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0019
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0019

24-Apr-1996	GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol Protocol Amendment: New Investigator	Investigator Add	0020
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Protocol
Protocol Amendment: New Investigator
Serial No.: 020

24-Apr-1996	Food and Drug Administration Correspondence	Comment/Information Request	Clinical	
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Comment/Information Request: Clinical

19-Jun-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 021	Protocol Amendment: New Investigator	Other 1572 Change	0021
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30-Nov-2001				
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)	Chronology	12:16:18

Date Range:	All			
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #

24-Jun-1996	GlaxoSmithKline Correspondence	Annual Report		0022
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CMC

Foreign Marketing Developments

IND 47,838; GI198745 5-Alpha Reductase Inhibitor
Annual Report
Serial No.: 022

29-Jul-1996	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Nonclinical	0023
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Response to FDA Request/Comment: Nonclinical
Serial No.: 0023

14-Aug-1996	GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol Protocol Amendment: New Investigator Protocol Amendment: Change in Protocol	Investigator Add Clinical	0024
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Protocol
Protocol Amendment: New Investigator
Protocol Amendment: Change in Protocol
Serial No.: 0024

JLP41868

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30-Nov-2001

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range:	Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
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29-Aug-1996		GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0025
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0025

11-Sep-1996		GlaxoSmithKline Correspondence	Protocol Amendment: Change in Protocol	Clinical	0026
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Serial No.: 026

02-Oct-1996		GlaxoSmithKline Correspondence	General Correspondence		0027
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence
Serial No.: 027

02-Oct-1996		GlaxoSmithKline Correspondence	General Correspondence	Other	
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence

09-Oct-1996		Food and Drug Administration Telephone Conversation	Comment/Information Request		
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**Regulatory Affairs
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13 30-Nov-2001 12:16:18

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date	Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
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"IND 47,838; GI198745 (5-alpha reductase inhibitor)
Information Request

15-Oct-1996	GlaxoSmithKline Correspondence	Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Clinical Investigator Add	0028
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Protocol Amendment: New Investigator
Serial No.: 028

15-Oct-1996	GlaxoSmithKline Telephone Conversation	General Teleconference	Meeting Request	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Meeting Request			

23-Oct-1996	GlaxoSmithKline Correspondence	General Correspondence	Meeting Agenda or Details	0029
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details Serial No.: 0029			

31-Oct-1996	Food and Drug Administration Correspondence	General Correspondence	Meeting Agenda or Details	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details			

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30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
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04-Nov-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: CMC Serial No.: 0030	General Correspondence	CMC	0030
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06-Nov-1996	Food and Drug Administration Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Clinical	Comment/Information Request	Clinical	
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15-Nov-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 0031	General Correspondence	Clinical	0031
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18-Nov-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical, Meeting Agenda or Details Serial No.: 0032	General Correspondence	Clinical Meeting Agenda or Details	0032
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26-Nov-1996	Food and Drug Administration Telephone Conversation	Comment/Information Request	Clinical Electronic Format	
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30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Comment/Information Request: Clinical, Electronic Format

18-Dec-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details Serial No.: 0033	General Correspondence	Meeting Agenda or Details	0033
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18-Dec-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 0034	General Correspondence	Clinical	0034
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28-Jan-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 035	Protocol Amendment: New Investigator	Other 1572 Change	0035
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30-Jan-1997	GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) Record of Telecon	General Teleconference	CMC	
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30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
10-Feb-1997		GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol Protocol Amendment: New Investigator	Investigator Add	0036
		IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Protocol Amendment: New Investigator Serial No.: 0036			
04-Mar-1997		GlaxoSmithKline Correspondence	Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Clinical Other 1572 Change	0037
		IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Serial No.: 0037			
05-Mar-1997		GlaxoSmithKline Correspondence	General Correspondence		0038
		IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 038			
20-Mar-1997		GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add	0039
		IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 039			

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JLP41868					
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30-Nov-2001					
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)			
Date Range:	All				
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #	
23-May-1997	GlaxoSmithKline Correspondence	General Correspondence		0040	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 040				
02-Jun-1997	GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol Protocol Amendment: New Investigator Information Amendment: Chemistry Manufacturing and Controls Protocol Amendment: Change in Protocol	Investigator Add CMC Clinical	0041	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Information Amendment: Chemistry Manufacturing and Controls Serial No.: 0041				
03-Jun-1997	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0042	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0042				

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30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range:	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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04-Jun-1997	"	GlaxoSmithKline Correspondence	General Correspondence		0043
IND 47,838; GI198745 (5-alpha reductase inhibitor)					
General Correspondence					
Serial No.: 043					

09-Jun-1997		GlaxoSmithKline Telephone Conversation	General Teleconference		
IND 47,838; GI198745 (5-alpha reductase inhibitor)					
Record of Telecon					

11-Jun-1997		GlaxoSmithKline Correspondence	Annual Report		0044
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CMC
Foreign Marketing Developments

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Annual Report
Serial No.: 044

02-Jul-1997		GlaxoSmithKline Correspondence	Information Amendment: Clinical		
IND 47,838; GI198745 (5-alpha reductase inhibitor)					
Information Amendment: Clinical					
Serial No.:045					

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30-Nov-2001

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Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Date Range:
Date

All

Communication Type

Document Type

Document Subtype

Serial / Supp #

22-Jul-1997

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add

0046

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 046

29-Jul-1997

GlaxoSmithKline Correspondence

General Correspondence

CMC

0047

IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence
Serial No.: 047

01-Aug-1997

GlaxoSmithKline Correspondence

General Correspondence

Other

IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence

07-Aug-1997

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Other 1572 Change

0048

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 048

13-Aug-1997

GlaxoSmithKline Correspondence

Protocol Amendment: New Protocol
Protocol Amendment: New Investigator
Amendment: Other

0049

Investigator Add
Transfer of Obligations to Contract

JLP41868

**Regulatory Affairs
CARDS**

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Chronology

30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Protocol
Protocol Amendment: New Investigator
Amendment: Other, Transfer of Obligations to Contract Research Organization
Serial No.: 0049

15-Aug-1997	GlaxoSmithKline Correspondence	Information Amendment: Chemistry Manufacturing and Controls		0050
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Information Amendment: Chemistry Manufacturing and Controls
Serial No.: 050

19-Aug-1997	Food and Drug Administration Correspondence	Comment/Information Request	CMC	
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Comment/Information Request: CMC

20-Aug-1997	GlaxoSmithKline Correspondence	Minutes of Meeting	End of Phase II Meeting	0051
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Minutes of Meeting
Serial No.: 051

28-Aug-1997	Food and Drug Administration Correspondence	Comment/Information Request		
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Comment/Information Request

JLP41868

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30-Nov-2001

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
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28-Aug-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 052	Protocol Amendment: New Investigator	Investigator Add	0052
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08-Sep-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 053	General Correspondence	Clinical	0053
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10-Sep-1997	Food and Drug Administration Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Minutes of Meeting: End of Phase II Meeting	Minutes of Meeting	End of Phase II Meeting	
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11-Sep-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Protocol Amendment: New Protocol Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Clinical Other 1572 Change	0054
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22
30-Nov-2001

Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range:	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
Date		Serial No.: 0054			

11-Sep-1997 GlaxoSmithKline Telephone Conversation General Teleconference

IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Teleconference

19-Sep-1997 GlaxoSmithKline Telephone Conversation General Teleconference

IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Teleconference

22-Sep-1997 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Investigator Add 0055
Other 1572 Change

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0055

25-Sep-1997 GlaxoSmithKline Correspondence Protocol Amendment: Change in Protocol Clinical 0056

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Serial No.: 56

Regulatory Affairs CARDS

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JLP41868

23

30-Nov-2001

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range:	Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
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01-Oct-1997
IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Teleconference: Draft Protocol

02-Oct-1997	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0057
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0057

09-Oct-1997	GlaxoSmithKline Correspondence	Information Amendment: Chemistry Manufacturing and Controls Information Amendment: Nonclinical	CMC Study Reports	0058
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Serial No.: 058
Information Amendment: Chemistry Manufacturing and Controls, CMC
Information Amendment: Nonclinical, Study Reports

10-Oct-1997	GlaxoSmithKline Correspondence	Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Clinical Investigator Add Other 1572 Change	0059
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Protocol Amendment: New Investigator
Serial No.: 0059

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30-Nov-2001

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
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Date	All			
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16-Oct-1997

GlaxoSmithKline Correspondence

Annual Report

Changes to Investigator's Brochure
Clinical Study Information
Clinical

0060

Protocol Amendment: Change in Protocol

21-Oct-1997

GlaxoSmithKline Correspondence

General Correspondence

Statistical

0061

IND 47,838; GI198745 (5-alpha reductase inhibitor)

General Correspondence

Serial No.: 061

24-Oct-1997

Food and Drug Administration Telephone
Conversation

Comment/Information Request

Clinical

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Comment/Information Request: Clinical

27-Oct-1997

GlaxoSmithKline Correspondence

Information Amendment: Chemistry Manufacturing
and Controls

0062

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Information Amendment: Chemistry Manufacturing and Controls

Serial No.: 062

JLP41868

**Regulatory Affairs
CARDS**

25

30-Nov-2001

Chronology

12:16:18

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All

Date **Communication Type**

Document Type

Document Subtype

Serial / Supp #

31-Oct-1997

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add
Other 1572 Change

0063

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0063

03-Nov-1997

GlaxoSmithKline Correspondence
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Serial No.: 064

Protocol Amendment: Change in Protocol

Clinical

0064

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Serial No.: 064

11-Nov-1997

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add
Other 1572 Change

0065

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0065

01-Dec-1997

Food and Drug Administration Telephone
Conversation

General Teleconference

Meeting Request

IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Teleconference

JLP41868

**Regulatory Affairs
CARDS**

26

30-Nov-2001

Chronology

12:16:18

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
02-Dec-1997	GlaxoSmithKline Telephone Conversation	Response to FDA Request/Comment	Statistical	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comment: Statistical			
03-Dec-1997	Food and Drug Administration Correspondence	Comment/Information Request	CMC	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Other			
05-Dec-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comments Serial No.: 067	Response to FDA Request/Comment	CMC	0067
05-Dec-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0066	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0066
08-Dec-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor)	Response to FDA Request/Comment	Clinical CMC	0068

JLP41868

**Regulatory Affairs
CARDS**

27

30-Nov-2001

Chronology

12:16:18

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range:	All	Document Type	Document Subtype	Serial / Supp #
Date	Communication Type			
	"General Correspondence			
	Serial No.: 068			

15-Dec-1997

GlaxoSmithKline FAX/E-mail

Response to FDA Request/Comment
General Memorandum

Statistical
Meeting Agenda or Details

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Response to FDA Request/Comment: Statistical

15-Dec-1997

Food and Drug Administration Telephone
Conversation

General Teleconference

Other

IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Teleconference: Other

08-Jan-1998

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add
Other 1572 Change

0069

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0069

22-Jan-1998

GlaxoSmithKline Correspondence
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Serial No.: 070

Protocol Amendment: Change in Protocol

Clinical

0070

Regulatory Affairs CARDS

Chronology

12:16:18

JLP41868
28

30-Nov-2001

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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29-Jan-1998	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0071
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0071

04-Feb-1998	GlaxoSmithKline Correspondence	General Correspondence	Statistical	0072
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence: Statistical
Serial No.: 072

11-Feb-1998	GlaxoSmithKline Correspondence	General Correspondence	Clinical Draft Protocol	0073
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence: Clinical
Serial No.: 073

18-Feb-1998	GlaxoSmithKline Correspondence	Information Amendment: Clinical	Other	0075
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Information Amendment: Clinical
Request for waivers for non-US Studies
Serial No.: 075

Regulatory Affairs CARDS

12:16:18

JLP41868
29
30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range: All
Date Communication Type Document Type Document Subtype Serial / Supp #

18-Feb-1998 GlaxoSmithKline Correspondence General Correspondence Statistical 0074
IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence
Serial No.: 074

26-Feb-1998 GlaxoSmithKline Correspondence Protocol Amendment: Change in Protocol Clinical
Protocol Amendment: New Investigator Investigator Add
Other 1572 Change 0076

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Protocol Amendment: New Investigator
Serial No.: 0076

06-Mar-1998 GlaxoSmithKline Correspondence Information Amendment: Chemistry Manufacturing and Controls CMC 0077
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Information Amendment: Chemistry Manufacturing and Controls, CMC
Serial No.: 077

27-Mar-1998 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Investigator Add
Other 1572 Change 0078
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0078

Regulatory Affairs CARDS

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JLP41868
30
30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)
Chronology

Date Range: All
Date Communication Type Document Type Document Subtype Serial / Supp #

02-Apr-1998 Food and Drug Administration Telephone Conversation
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Comment/Information Request: Clinical
Comment/Information Request: Clinical
Comment/Information Request: Clinical
Clinical

03-Apr-1998 Food and Drug Administration Telephone Conversation
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Comment/Information Request
Comment/Information Request
Statistical

09-Apr-1998 GlaxoSmithKline Telephone Conversation
IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Teleconference: CMC
General Teleconference
CMC

17-Apr-1998 Food and Drug Administration Correspondence
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Comment/Information Request: Clinical
Comment/Information Request
Clinical

23-Apr-1998 GlaxoSmithKline Telephone Conversation
IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Teleconference
CMC

JLP41868

**Regulatory Affairs
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31
30-Nov-2001
Application: IND
IND 47838; GI198745 (5-alpha reductase inhibitor)
Chronology
12:16:18

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
Date	"General Teleconference: CMC			

27-Apr-1998	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0079
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0079

28-Apr-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 080	Protocol Amendment: Change in Protocol	Clinical	0080
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30-Apr-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 081	Protocol Amendment: Change in Protocol	Clinical	0081
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11-May-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 082	General Correspondence	Clinical	0082
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JLP41868

**Regulatory Affairs
CARDS**

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Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range:	All	Document Type	Document Subtype	Serial / Supp #
Date	Communication Type			
12-May-1998	Food and Drug Administration Telephone Conversation	Comment/Information Request	Clinical Protocol	

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Comment/Information Request: Clinical, Protocol

28-May-1998 Food and Drug Administration Correspondence Comment/Information Request

Clinical
Statistical

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Comment/Information Request: Clinical, Statistical

29-May-1998 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator

Investigator Add
Other 1572 Change

0083

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0083

29-May-1998 GlaxoSmithKline Telephone Conversation Response to FDA Request/Comment

Clinical
Protocol

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Response to FDA Request/Comment: Clinical

Regulatory Affairs CARDS

Chronology

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JLP41868
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30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date	Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
	All				

09-Jun-1998		GlaxoSmithKline Correspondence	Annual Report	Adverse Event Summary Clinical Study Information CMC Outstanding Regulatory Business	0084
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Annual Report
Serial No.: 084

19-Jun-1998		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 085	General Correspondence	Clinical	0085
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22-Jun-1998		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Serial No.: 086	Protocol Amendment: New Protocol		0086
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23-Jun-1998		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor)	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0087
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Regulatory Affairs CARDS

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JLP41868

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30-Nov-2001

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range:	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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Protocol Amendment: New Investigator
Serial No.: 0087

01-Jul-1998	GlaxoSmithKline Correspondence	Information Amendment: Chemistry Manufacturing and Controls	CMC	0088
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Information Amendment: Chemistry Manufacturing and Controls
Serial No.: 088

09-Jul-1998	GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Clinical Investigator Add	0089
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Protocol
Protocol Amendment: Change in Protocol
Protocol Amendment: New Investigator
Serial No.: 0089

31-Jul-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 0090	Protocol Amendment: Change in Protocol	Clinical	0090
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03-Aug-1998	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0091
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Chronology

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47838; GI198745 (5-alpha reductase inhibitor)

Communication Type	Document Type	Document Subtype	Serial / Supp #
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0091

10-Aug-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 092	Protocol Amendment: Change in Protocol	Clinical	0092
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31-Aug-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0093	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0093
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14-Sep-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0094	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0094
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06-Oct-1998	GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Serial No.: 0095	Protocol Amendment: New Investigator		0095
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JLP41868

**Regulatory Affairs
CARDS**

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30-Nov-2001

Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All

Date Communication Type

Document Type

Document Subtype

Serial / Supp #

Investigator Add

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Protocol
Protocol Amendment: New Investigator
Serial No.: 0095

13-Oct-1998 GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add
Other 1572 Change

0096

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0096

28-Oct-1998 GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add
Other 1572 Change

0097

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0097

06-Nov-1998 GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add
Other 1572 Change

0098

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0098

Regulatory Affairs CARDS

Chronology

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JLP41868
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30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
All				
10-Nov-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 099	Protocol Amendment: Change in Protocol	Clinical	0099
18-Nov-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0100	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0100
17-Dec-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0101	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0101
22-Dec-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0102	Protocol Amendment: New Investigator	Other 1572 Change	0102
23-Dec-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor)	Protocol Amendment: New Investigator	Investigator Add	0103

Regulatory Affairs CARDS

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JLP4186838									
30-Nov-2001									
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)	Chronology						
Date Range:	All								
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #					
	Protocol Amendment: New Investigator								
	Serial No.: 103								
13-Jan-1999	GlaxoSmithKline Correspondence	Information Amendment: Chemistry Manufacturing and Controls	CMC	0104					
	IND 47,838; GI198745 (5-alpha reductase inhibitor)								
	Information Amendment: Chemistry Manufacturing and Controls, CMC								
	Serial No.: 104								
15-Jan-1999	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0105					
	IND 47,838; GI198745 (5-alpha reductase inhibitor)								
	Protocol Amendment: New Investigator								
	Serial No.: 0105								
02-Feb-1999	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0106					
	IND 47,838; GI198745 (5-alpha reductase inhibitor)								
	Protocol Amendment: New Investigator								
	Serial No.: 0106								
18-Feb-1999	GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol Protocol Amendment: New Investigator	Investigator Add	0107					
	IND 47,838; GI198745 (5-alpha reductase inhibitor)								

JLP41868

**Regulatory Affairs
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30-Nov-2001

Chronology

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Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Date Range:
Date

All

Communication Type

Document Type

Document Subtype

Serial / Supp #

Protocol Amendment: New Protocol
Protocol Amendment: New Investigator
Serial No.: 0107

03-Mar-1999

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add
Other 1572 Change

0108

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0108

04-Mar-1999

GlaxoSmithKline Correspondence

Information Amendment: Chemistry Manufacturing
and Controls

CMC

0109

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Information Amendment: Chemistry Manufacturing and Controls, CMC
Serial No.: 109

08-Mar-1999

GlaxoSmithKline Correspondence

Protocol Amendment: New Protocol
Protocol Amendment: New Investigator

Investigator Add

0110

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Protocol
Protocol Amendment: New Investigator
Serial No.: 110

12-Mar-1999

GlaxoSmithKline Correspondence
IND 47,838; GI198745 (5-alpha reductase inhibitor)

Protocol Amendment: Change in Protocol

Clinical

0111

Regulatory Affairs CARDS

Chronology

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JLP41868					
40					
30-Nov-2001					
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)			
Date Range:	All				
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #	
	"Protocol Amendment: Change in Protocol Serial No.: 111				
19-Mar-1999	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0112	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0112				
02-Apr-1999	GlaxoSmithKline Correspondence	Amendment: Other	Change in Medical Monitor	0113	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Amendment: Other, Change in Medical Monitor Serial No.: 113				
06-Apr-1999	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Other 1572 Change	0114	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 114				
27-Apr-1999	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Other 1572 Change	0115	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0115				

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**Regulatory Affairs
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30-Nov-2001
Application: IND
IND 47838; GI198745 (5-alpha reductase inhibitor)
Chronology
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Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
29-Apr-1999	GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: CMC	General Teleconference	CMC	
19-May-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Statistical Serial No.: 0116	General Correspondence	Statistical	0116
21-May-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0117	Protocol Amendment: New Investigator	Other 1572 Change	0117
09-Jun-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Serial No.: 0119	Protocol Amendment: New Protocol Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Clinical Investigator Add	0119

JLP41868

**Regulatory Affairs
CARDS**

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30-Nov-2001

Chronology

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Application:

IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All

Date Communication Type

Document Type

Document Subtype

Serial / Supp #

09-Jun-1999

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add
Other 1572 Change

0118
0018

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0118

10-Jun-1999

Food and Drug Administration Telephone
Conversation
IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Teleconference: Status Update

General Teleconference

Status Update

22-Jun-1999

GlaxoSmithKline Correspondence

Annual Report

Adverse Event Summary
Clinical Study Information
CMC
Investigational Plan
Outstanding Regulatory Business

0120

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Annual Report
Serial No.: 0120

24-Jun-1999

GlaxoSmithKline Correspondence
IND 47,838; GI198745 (5-alpha reductase inhibitor) Injection, 0.0111 mg GI198745X per mL
General Correspondence: CMC -Phase I IV Solution

General Correspondence

CMC

0121

JLP41868

**Regulatory Affairs
CARDS**

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30-Nov-2001

Chronology

12:16:18

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range:	Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
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All
Serial No.: 0121

24-Jun-1999	GlaxoSmithKline Correspondence	General Correspondence	CMC	0122
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IND 47,838; GI198745 Soft Gelatin Capsules, 0.5 mg
General Correspondence: CMC - Specification and Test Methods
Serial No.: 0122

02-Jul-1999	GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol Protocol Amendment: New Investigator	Investigator Add	0123
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Protocol
Protocol Amendment: New Investigator
Serial No.: 0123

06-Jul-1999	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Other 1572 Change	0124
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0124

15-Jul-1999	Food and Drug Administration Telephone Conversation	Comment/Information Request	Other	
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Comment/Information Request: Other

Regulatory Affairs CARDS

12:16:18

JLP41868					
44					
30-Nov-2001					
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)	Chronology		
Date Range:	All				
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #	
20-Jul-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0125	Protocol Amendment: New Investigator	Other 1572 Change	0125	
21-Jul-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 0126	Protocol Amendment: Change in Protocol	Clinical	0126	
22-Jul-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 0127	General Correspondence	Clinical	0127	
30-Jul-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0128	Protocol Amendment: New Investigator	Other 1572 Change	0128	
17-Aug-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0129	Protocol Amendment: New Investigator	Other 1572 Change	0129	

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30-Nov-2001
Application: IND
Date Range: All
Date
IND
47838; GI198745 (5-alpha reductase inhibitor)
Chronology
Regulatory Affairs
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Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
01-Sep-1999	GlaxoSmithKline Correspondence	Information Amendment: Chemistry Manufacturing and Controls	CMC	0130
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Chemistry Manufacturing and Controls, CMC Serial No.: 0130			
01-Sep-1999	GlaxoSmithKline Telephone Conversation	General Teleconference	Clinical Safety	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Clinical, Safety			
09-Sep-1999	GlaxoSmithKline Correspondence	General Correspondence	Meeting Agenda or Details	0131
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details Serial No.: 0131			
	IND 53,551; GI262570X General Correspondence: Meeting Agenda or Details Serial No.: 0072			
10-Sep-1999	Food and Drug Administration Telephone Conversation	General Teleconference	Status Update	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Status Update			

Regulatory Affairs CARDS

JLP41868

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30-Nov-2001

Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Chronology

12:16:18

Date Range: All

Date

Communication Type

Document Type

Document Subtype

Serial / Supp #

24-Sep-1999

GlaxoSmithKline Correspondence

15-Day ADR Report

Initial

0132

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 0132

IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia

Serial No.: 0021

10-Day ADR Report: Initial

26-Oct-1999

GlaxoSmithKline Correspondence

Improper Conduct by an Investigator

0133

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Improper Conduct by an Investigator

Serial No.: 0133

28-Oct-1999

GlaxoSmithKline Correspondence

General Correspondence

Statistical

0134

IND 47,838; GI198745 (5-alpha reductase inhibitor)

General Correspondence: Statistical

Serial No.: 0134

28-Oct-1999

GlaxoSmithKline Correspondence

Minutes of Meeting

FDA Conference

0135

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Minutes of Meeting

Serial No.: 0135

28-Oct-1999

GlaxoSmithKline Correspondence

15-Day ADR Report

Initial

0136

IND 47,838; GI198745 (5-alpha reductase inhibitor)

JLP41868

**Regulatory Affairs
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30-Nov-2001

Chronology

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Application:

IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range:
Date

All
Communication Type
Document Type
Document Subtype
Serial / Supp #

Serial No.: 0136
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia
Serial No.: 0023
10-Day ADR Report: Initial

01-Nov-1999

GlaxoSmithKline Correspondence

Protocol Amendment: New Protocol
Protocol Amendment: New Investigator

0137

Investigator Add

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Protocol
Protocol Amendment: New Investigator
Serial No.: 0137

02-Nov-1999

GlaxoSmithKline Correspondence

Information Amendment: Clinical

Statistical

0138

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Information Amendment: Clinical, Statistical
Serial No.: 0138

10-Nov-1999

GlaxoSmithKline Correspondence

General Correspondence

Clinical

0139

IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence
Serial No.: 0139

22-Nov-1999

GlaxoSmithKline Correspondence

Protocol Amendment: Change in Protocol

Clinical

0140

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Serial No.: 0140

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30-Nov-2001

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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03-Dec-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 0141	Protocol Amendment: Change in Protocol	Clinical	0141
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08-Dec-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0142	Protocol Amendment: New Investigator	Investigator Add	0142
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10-Dec-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0143 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0024 10-Day ADR Report: Follow-up	15-Day ADR Report	Follow-up	0143
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15-Dec-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0144	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0144
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JLP41868
49
30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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22-Dec-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Statistical Serial No.: 0145	General Correspondence	Statistical	0145
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28-Dec-1999	Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Statistical	Comment/Information Request	Statistical	
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05-Jan-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0146 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0025 10-Day ADR Report: Initial	15-Day ADR Report	Initial	0146
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05-Jan-2000	Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Other	General Teleconference	Other	
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06-Jan-2000	Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Other	General Teleconference	Other	
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JLP41868

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CARDS

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Chronology

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Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All
Date

Communication Type

Document Type

Document Subtype

Serial / Supp #

10-Jan-2000

Food and Drug Administration Telephone
Conversation
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Comment/Information Request: Other

Comment/Information Request

Other

11-Jan-2000

GlaxoSmithKline Correspondence

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0147

Protocol Amendment: New Investigator

Other 1572 Change
Investigator Add

0147

11-Jan-2000

GlaxoSmithKline Telephone Conversation

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Response to FDA Request/Comment: Safety

Response to FDA Request/Comment

Safety

17-Jan-2000

GlaxoSmithKline FAX/E-mail

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Response to FDA Request/Comment: Other

Response to FDA Request/Comment

Other

19-Jan-2000

GlaxoSmithKline Correspondence

15-Day ADR Report

Follow-up

0148

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range:	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
		IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0148			
		IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0027			
		10-Day ADR Report: Follow-up			

02-Feb-2000 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Investigator Add
Other 1572 Change 0150

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0150

02-Feb-2000 GlaxoSmithKline Correspondence 15-Day ADR Report Initial 0149

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Serial No.: 0149
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia
Serial No.: 0028
10-Day ADR Report: Initial

24-Feb-2000 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Investigator Add
Other 1572 Change 0151

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0151

JLP41868

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CARDS**

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30-Nov-2001

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All

Communication Type

Document Type

Document Subtype

Serial / Supp #

14-Mar-2000

GlaxoSmithKline Correspondence
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Amendment: Other, Letter of Authorization
Serial No.: 0153

Amendment: Other

Letter of Authorization

0153

14-Mar-2000

GlaxoSmithKline Correspondence

Protocol Amendment: Change in Protocol
Protocol Amendment: New Investigator

Clinical
Investigator Add

0152

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Protocol Amendment: New Investigator
Serial No.: 0152

30-Mar-2000

GlaxoSmithKline Correspondence
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Serial No.: 0154
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia
Serial No.: 0030
10-Day ADR Report: Follow-up

15-Day ADR Report

Follow-up

0154

14-Apr-2000

GlaxoSmithKline Correspondence
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0155

Protocol Amendment: New Investigator

Investigator Add

0155

21-Apr-2000

Food and Drug Administration Telephone
Conversation

General Teleconference

Other

**Regulatory Affairs
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30-Nov-2001

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range:	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Teleconference: Other

03-May-2000	GlaxoSmithKline Correspondence	15-Day ADR Report	Initial	0156
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Serial No.: 0156
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia
Serial No.: 0031
10-Day ADR Report: Initial

05-May-2000	GlaxoSmithKline Correspondence	15-Day ADR Report	Follow-up	0157
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Serial No.: 0157
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia
Serial No.: 0032
10-Day ADR Report: Follow-up

19-May-2000	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0158
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0158

23-May-2000	GlaxoSmithKline FAX/E-mail	General Memorandum	Safety
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**Regulatory Affairs
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54
30-Nov-2001
Application: IND
47838; GI198745 (5-alpha reductase inhibitor)
Chronology
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Date Range: All
Date
Communication Type
Document Type
Document Subtype
Serial / Supp #

23-May-2000
GlaxoSmithKline Telephone Conversation
7-Day Safety Report
Safety
IND 47,838; GI198745 (5-alpha reductase inhibitor)
7-Day Safety Report

24-May-2000
GlaxoSmithKline Correspondence
15-Day ADR Report
Initial
0159
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Serial No.: 0159
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia
Serial No.: 0033
10-Day ADR Report: Initial

09-Jun-2000
GlaxoSmithKline Correspondence
15-Day ADR Report
Follow-up
0160
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Serial No.: 0160
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia
Serial No.: 0034
10-Day ADR Report: Follow-up

15-Jun-2000
GlaxoSmithKline Correspondence
Protocol Amendment: New Investigator
Other 1572 Change
0161
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0161

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30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range: All
Date Communication Type Document Type Document Subtype Serial / Supp #

23-Jun-2000 GlaxoSmithKline Correspondence 15-Day ADR Report Follow-up 0162
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Serial No.: 0162
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia
Serial No.: 0035
10-Day ADR Report: Follow-up

27-Jun-2000 GlaxoSmithKline Correspondence Annual Report Clinical Study Information Investigational Plan 0163

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Annual Report
Serial No.: 0163

13-Jul-2000 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Investigator Add Other 1572 Change 0164

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0164

13-Jul-2000 GlaxoSmithKline Correspondence 15-Day ADR Report Follow-up 0165

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Serial No.: 0165
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia
Serial No.: 0036
10-Day ADR Report: Follow-up

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30-Nov-2001

Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All

Date Communication Type

Document Type

Document Subtype

Serial / Supp #

17-Jul-2000 GlaxoSmithKline Telephone Conversation

7-Day Safety Report

Safety

IND 47,838; GI198745 (5-alpha reductase inhibitor)
7-Day Safety Report

18-Jul-2000 GlaxoSmithKline Correspondence

15-Day ADR Report

Initial

0166

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Serial No.: 0166
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia
Serial No.: 0037
10-Day ADR Report: Initial

08-Aug-2000 GlaxoSmithKline Correspondence

Protocol Amendment: Change in Protocol

Clinical

0167

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Serial No.: 0167

16-Aug-2000 GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add
Other 1572 Change

0168

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0168

Regulatory Affairs CARDS

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30-Nov-2001

Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Chronology

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Date Range:	Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
17-Aug-2000	All	GlaxoSmithKline Correspondence	15-Day ADR Report	Follow-up	0169

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 0169

IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia

Serial No.: 0038

10-Day ADR Report: Follow-up

21-Aug-2000	GlaxoSmithKline Telephone Conversation	7-Day Safety Report	Safety
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IND 47,838; GI198745 (5-alpha reductase inhibitor)

7-Day Safety Report

22-Aug-2000	GlaxoSmithKline Correspondence	15-Day ADR Report	Initial	0170
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IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 0170

IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia

Serial No.: 0039

10-Day ADR Report: Initial

24-Aug-2000	GlaxoSmithKline Correspondence	15-Day ADR Report	Initial	0171
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IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 0171

IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia

Serial No.: 0040

10-Day ADR Report: Initial

24-Aug-2000	GlaxoSmithKline Correspondence	Information Amendment: Clinical	Other	0172
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Regulatory Affairs CARDS

Chronology

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58				
30-Nov-2001				
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)		
Date Range:	All			
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
		General Correspondence	Draft Protocol	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	Information Amendment: Clinical, Other			
	Serial No.: 0172			
28-Aug-2000	GlaxoSmithKline Correspondence	General Correspondence	CMC	0173
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	General Correspondence: CMC			
	Serial No.: 0173			
19-Sep-2000	GlaxoSmithKline Correspondence	General Correspondence	Clinical	0174
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	General Correspondence: Clinical			
	Serial No.: 0174			
20-Sep-2000	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0175
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	Protocol Amendment: New Investigator			
	Serial No.: 0175			
22-Sep-2000	GlaxoSmithKline Correspondence	General Correspondence	Meeting Request	0176
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	General Correspondence: Meeting Request			
	Serial No.: 0176			

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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26-Sep-2000	GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol Protocol Amendment: New Investigator	Investigator Add	0177
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Protocol
Serial No.: 0177

26-Sep-2000

Food and Drug Administration Telephone
Conversation
IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Teleconference: Status Update

General Teleconference

Status Update

27-Sep-2000

GlaxoSmithKline Correspondence
IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence: CMC Meeting Request
Serial No.: 0178

General Correspondence

CMC

0178

03-Oct-2000

Food and Drug Administration Telephone
Conversation
IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Teleconference: Meeting Request

General Teleconference

Meeting Request

06-Oct-2000

Food and Drug Administration Correspondence

General Correspondence

Meeting Agenda or Details

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30-Nov-2001					
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)		Chronology	
Date Range:	All				
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	General Correspondence: Meeting Agenda or Details				
13-Oct-2000	GlaxoSmithKline Telephone Conversation	General Teleconference	CMC Meeting Agenda or Details		
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	General Teleconference: CMC, Meeting Agenda or Details				
17-Oct-2000	Food and Drug Administration Correspondence	Comment/Information Request	Clinical Protocol		
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	Comment/Information Request				
17-Oct-2000	Food and Drug Administration Correspondence	Comment/Information Request	Clinical		
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	Comment/Information Request				
19-Oct-2000	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change		0179

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30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor) Chronology 12:16:18

Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0179

23-Oct-2000	Food and Drug Administration FAX/E-mail	General Memorandum Comment/Information Request	Meeting Agenda or Details CMC	
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Memorandum: Meeting Agenda or Details
Comment/Information Request: CMC

27-Oct-2000	GlaxoSmithKline Correspondence	General Correspondence	Clinical Meeting Agenda or Details Nonclinical Protocol	0180
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence: Meeting Agenda or Details
Pre-NDA Meeting Information Package
Serial No.: 0180

30-Oct-2000	GlaxoSmithKline Correspondence	Protocol Amendment: Change in Protocol	Clinical	0181
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Serial No.: 0181

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JLP41868
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30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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02-Nov-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 0182	Protocol Amendment: Change in Protocol	Clinical	0182
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06-Nov-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0183 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0041 10-Day ADR Report: Initial	15-Day ADR Report	Initial	0183
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07-Nov-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Clinical, Statistical Serial No.: 0184	Information Amendment: Clinical	Statistical	0184
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09-Nov-2000	GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: CMC	General Teleconference	CMC Meeting Agenda or Details	
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Chronology

30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
09-Nov-2000	Food and Drug Administration Correspondence	General Correspondence	Meeting Agenda or Details	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details			
17-Nov-2000	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0185
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0185			
17-Nov-2000	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	CMC	0186
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comment: CMC Serial No.: 0186			
27-Nov-2000	Food and Drug Administration Telephone Conversation	Comment/Information Request	Clinical	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Clinical Comment on Pre-NDA Meeting Package			
30-Nov-2000	GlaxoSmithKline Correspondence	15-Day ADR Report	Follow-up	0187
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0187 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia			

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30-Nov-2001

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range:	Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
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All
Serial No.: 0042
10-Day ADR Report: Follow-up

01-Dec-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 0188	Protocol Amendment: Change in Protocol	Clinical	0188
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05-Dec-2000	GlaxoSmithKline Trip Report IND 47,838; GI198745 (5-alpha reductase inhibitor) Type: Pre-NDA Meeting	Type	Pre-NDA Meeting	
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05-Dec-2000	Food and Drug Administration Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details	General Correspondence	Meeting Agenda or Details	
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06-Dec-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details Serial No.: 0189	General Correspondence	Meeting Agenda or Details	0189
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08-Dec-2000	GlaxoSmithKline Correspondence	General Correspondence	Nonclinical	0190
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Regulatory Affairs CARDS

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JLP41868					
65					
30-Nov-2001					
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)	Chronology		
Date Range:	All				
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #	
	"IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Nonclinical Serial No.: 0190				
14-Dec-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0191	Protocol Amendment: New Investigator	Other 1572 Change	0191	
15-Dec-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comment: Clinical, Draft Protocol Serial No.: 0192	Response to FDA Request/Comment	Clinical Draft Protocol	0192	
18-Dec-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0193 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0043 10-Day ADR Report: Follow-up	15-Day ADR Report	Follow-up	0193	
02-Jan-2001	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0194 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia	15-Day ADR Report	Initial	0194	

Regulatory Affairs CARDS

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30-Nov-2001						
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)	Chronology			
Date Range:	All					
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #		
	Serial No.: 0044					
	10-Day ADR Report: Initial					
03-Jan-2001	Food and Drug Administration Correspondence	Comment/Information Request			Statistical	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)					
	Comment/Information Request: Statistical					
08-Jan-2001	GlaxoSmithKline Correspondence	15-Day ADR Report			Follow-up	0195
	IND 47,838; GI198745 (5-alpha reductase inhibitor)					
	Serial No.: 0195					
	IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia					
	Serial No.: 0045					
	10-Day ADR Report: Follow-up					
09-Jan-2001	GlaxoSmithKline Telephone Conversation	7-Day Safety Report			Safety	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)					
	7-Day Safety Report					
10-Jan-2001	GlaxoSmithKline Correspondence	15-Day ADR Report			Initial	0196
	IND 47,838; GI198745 (5-alpha reductase inhibitor)					
	Serial No.: 0196					
	IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia					
	Serial No.: 0046					
	10-Day ADR Report: Initial					

Regulatory Affairs CARDS

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30-Nov-2001

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date	Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
	All				

11-Jan-2001		GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0197
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0197

12-Jan-2001		GlaxoSmithKline Correspondence	15-Day ADR Report	Follow-up	0198
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Serial No.: 0198
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia
Serial No.: 0048
10-Day ADR Report: Follow-up

02-Feb-2001		GlaxoSmithKline Correspondence	Response to FDA Request/Comment	CMC	0199
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Response to FDA Request/Comment: CMC Teleconference Held on November 9, 2000
Serial No.: 0199

08-Feb-2001		GlaxoSmithKline Correspondence	Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Clinical Investigator Add Other 1572 Change	0200
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Protocol Amendment: New Investigator

Regulatory Affairs CARDS

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JLP41868					
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30-Nov-2001					
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)	Chronology		
Date Range:	All				
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #	
	Serial No.: 0200				
08-Feb-2001	GlaxoSmithKline Telephone Conversation	General Teleconference	CMC		
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	General Teleconference: CMC				
19-Feb-2001	GlaxoSmithKline Correspondence	15-Day ADR Report	Initial	0201	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	Serial No.: 0201				
	IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia				
	Serial No.: 0049				
	10-Day ADR Report: Initial				
05-Mar-2001	GlaxoSmithKline Correspondence	15-Day ADR Report	Follow-up	0202	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	Serial No.: 0202				
	IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia				
	Serial No.: 0050				
	10-Day ADR Report: Follow-up				
09-Mar-2001	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Other 1572 Change	0203	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	Protocol Amendment: New Investigator				
	Serial No.: 0203				

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30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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30-Mar-2001	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Clinical Serial No.: 0204	Information Amendment: Clinical	Other	0204
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09-Apr-2001	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0205	Protocol Amendment: New Investigator	Other 1572 Change	0205
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08-May-2001	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0206	Protocol Amendment: New Investigator	Other 1572 Change	0206
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07-Jun-2001	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0207	Protocol Amendment: New Investigator	Other 1572 Change	0207
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21-Jun-2001	GlaxoSmithKline Correspondence	Annual Report	Adverse Event Summary Changes to Investigator's Brochure Clinical Study Information CMC	0208
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JLP41868
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30-Nov-2001
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date	Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
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IND 47,838; GI198745 (5-alpha reductase inhibitor)
Annual Report
Serial No.: 0208

18-Jul-2001		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0209	15-Day ADR Report	Initial	0209
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IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia
Serial No.: 0051
15-Day ADR Report: Initial

25-Jul-2001		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0210	Protocol Amendment: New Investigator	Other 1572 Change	0210
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27-Jul-2001		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0211 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0052 15-Day ADR Report: Follow-up	15-Day ADR Report	Follow-up	0211
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06-Aug-2001		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0212	15-Day ADR Report	Follow-up	0212
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30-Nov-2001

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

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Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
Date Range: All				
	IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0053			
	15-Day ADR Report: Follow-up			
31-Aug-2001	GlaxoSmithKline Correspondence IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0054 IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0213 General Correspondence: Clinical	General Correspondence	Clinical	0213
05-Sep-2001	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0214 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0055 15-Day ADR Report: Initial	15-Day ADR Report	Initial	0214
06-Sep-2001	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0215	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0215
20-Sep-2001	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor)	15-Day ADR Report	Follow-up	0216

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Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Date Range:
Date

All

Communication Type

Document Type

Document Subtype

Serial / Supp #

Serial No.: 0216

IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia

Serial No.: 0056

15-Day ADR Report: Follow-up

08-Oct-2001

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Other 1572 Change

0217

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Protocol Amendment: New Investigator

Serial No.: 0217

07-Nov-2001

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Other 1572 Change

0218

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Protocol Amendment: New Investigator

Serial No.: 0218

30-Nov-2001

GlaxoSmithKline Correspondence

General Correspondence

0219

NAS; Not Product Specific
General Correspondence: Other

EXHIBIT 8B

Document Chronology/Due Diligence Logs for NDA 21-319

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JLP41868
30-Nov-2001
Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range:	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
22-Sep-2000		Food and Drug Administration FAX/E-mail	General Memorandum	Status Update	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules General Memorandum: User Fee ID #			
06-Oct-2000		Food and Drug Administration Correspondence	General Correspondence	Meeting Agenda or Details	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: Meeting Agenda or Details			
19-Dec-2000		GlaxoSmithKline Correspondence	User Fee	Establishment With Clinical Data	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules User Fee ID Number 4030: Establishment With Clinical Data			
19-Dec-2000		Food and Drug Administration Telephone Conversation	General Teleconference	Status Update	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules General Teleconference: Status Update			
19-Dec-2000		GlaxoSmithKline Telephone Conversation	General Teleconference	Request Status Update	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules General Teleconference: Request Status Update			

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30-Nov-2001
Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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21-Dec-2000	GlaxoSmithKline Correspondence	General Correspondence	CMC Field Copy	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC Field Copy			

21-Dec-2000	GlaxoSmithKline Correspondence	Original Submission User Fee General Correspondence	Establishment Clinical CMC Field Copy DMF Nonclinical Patent Information	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Original Submission

02-Jan-2001	Food and Drug Administration Telephone Conversation NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request: Desk Copies	Comment/Information Request	Other	
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JLP41868 30-Nov-2001 Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

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Date	Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
	All				
03-Jan-2001		GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Other	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Desk Copies			
26-Jan-2001		GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Clinical Statistical	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment			
01-Feb-2001		GlaxoSmithKline Telephone Conversation	Response to FDA Request/Comment	CMC	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: CMC			
01-Feb-2001		GlaxoSmithKline Telephone Conversation	Response to FDA Request/Comment	CMC	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: CMC			

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JLP41868 30-Nov-2001 Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

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Date Range: All Date Communication Type Document Type Document Subtype Serial / Supp #

02-Feb-2001 "GlaxoSmithKline Telephone Conversation Response to FDA Request/Comment CMC

NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment: CMC

06-Feb-2001 Food and Drug Administration Telephone Conversation Comment/Information Request Clinical Statistical

NDA 21-319; Dutasteride Soft-Gelatin Capsules
Comment/Information Request

08-Feb-2001 Food and Drug Administration Telephone Conversation Comment/Information Request CMC Electronic Format Nonclinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules
Comment/Information Request

08-Feb-2001 GlaxoSmithKline Telephone Conversation General Teleconference Clinical CMC Meeting Agenda or Details

NDA 21-319; Dutasteride Soft-Gelatin Capsules

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Application: NDA 21319; Dutasteride Soft-Gelatin Capsules
Date Range: All
Date Communication Type Document Type Document Subtype Serial / Supp #

"General Teleconference: Meeting Agenda or Details"

13-Feb-2001 GlaxoSmithKline Correspondence Response to FDA Request/Comment Clinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request for Information on Clinical Investigators

21-Feb-2001 GlaxoSmithKline Correspondence General Correspondence Meeting Agenda or Details
Other

NDA 21-319; Dutasteride Soft-Gelatin Capsules
General Correspondence: Meeting Agenda or Details, Other

01-Mar-2001 GlaxoSmithKline Correspondence Response to FDA Request/Comment Clinical
CMC
Nonclinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment

20-Apr-2001 GlaxoSmithKline Correspondence 120-Day Safety Update Safety

NDA 21-319; Dutasteride Soft-Gelatin Capsules

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30-Nov-2001
Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
"120-Day Safety Update: Safety				
07-May-2001	GlaxoSmithKline FAX/E-mail NDA 21-319; Dutasteride Soft-Gelatin Capsules General Memorandum: CMC	General Memorandum	CMC	
08-May-2001	GlaxoSmithKline Telephone Conversation NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Nonclinical	Response to FDA Request/Comment	Nonclinical	
08-May-2001	Food and Drug Administration Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Minutes of Meeting	Minutes of Meeting	FDA Conference	
09-May-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC	General Correspondence	CMC	
15-May-2001	GlaxoSmithKline Correspondence	General Correspondence	CMC	

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Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date	Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
General Correspondence: CMC

12-Jun-2001		GlaxoSmithKline Telephone Conversation	General Teleconference	CMC	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
General Teleconference: CMC

12-Jun-2001		Food and Drug Administration Correspondence	Minutes of Meeting Comment/Information Request	FDA Conference CMC	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Minutes of Meeting: FDA Conference

14-Jun-2001		GlaxoSmithKline Telephone Conversation	General Teleconference	CMC	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
General Teleconference: CMC

15-Jun-2001		GlaxoSmithKline Correspondence	Amendment to Pending Application	Clinical Nonclinical	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules

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Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
All				
"Amendment to Pending Application: Clinical, Nonclinical				
27-Jun-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	CMC	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: CMC-Site Change for the Blister Pack Foil Lidding			
27-Jun-2001	GlaxoSmithKline Correspondence	General Correspondence	CMC	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC Meeting Minutes for June 14, 2001			
27-Jun-2001	GlaxoSmithKline Correspondence	General Correspondence	CMC Field Copy	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC Field Copy			
27-Jun-2001	GlaxoSmithKline Correspondence	General Correspondence	CMC	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC - 36-Month Stability Update			
27-Jun-2001	GlaxoSmithKline Correspondence	User Fee	Response to Reconciliation Request	

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Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
	FDA Invoice 975586 User Fee: Response to Reconciliation Request			
	NDA 19-958; CUTIVATE® (fluticasone propionate cream) Cream, 0.05% NDA 21-254; ADVAIR™ HFA (fluticasone propionate/salmeterol) Inhalation Aerosol 44mcg/21mcg, 110mcg/21mcg, 220mcg/21mcg NDA 21-319; Dutasteride Soft-Gelatin Capsules			
27-Jun-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC Field Copy	General Correspondence	CMC Field Copy	
02-Jul-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Other, Financial Disclosure	Response to FDA Request/Comment	Other	
02-Jul-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Nonclinical	Response to FDA Request/Comment	Nonclinical	
09-Jul-2001	GlaxoSmithKline Correspondence	Amendment to Pending Application	Labeling	

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Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

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Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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NDA 21-319; Dutasteride Soft-Gelatin Capsules				
Amendment to Pending Application: Tradename; Labeling				

13-Jul-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Labeling	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules				
Response to FDA Request/Comment: Labeling				

16-Jul-2001	GlaxoSmithKline Telephone Conversation	General Teleconference	CMC	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules				
General Teleconference: CMC				

16-Jul-2001	GlaxoSmithKline Correspondence	Minutes of Meeting	FDA Conference	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules				
Minutes of Meeting				

20-Jul-2001	GlaxoSmithKline Correspondence	Amendment to Pending Application	Clinical Labeling Nonclinical	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules				
Amendment to Pending Application: Labeling, Nonclinical, Human Pharmacokinetics				

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Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
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20-Jul-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Statistical	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment: Statistical

26-Jul-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Nonclinical	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment: Nonclinical

30-Jul-2001	GlaxoSmithKline Telephone Conversation	Response to FDA Request/Comment	Nonclinical	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment

30-Jul-2001	Food and Drug Administration Correspondence	Minutes of Meeting	FDA Conference	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Minutes of Meeting

02-Aug-2001	Food and Drug Administration FAX/E-mail	Comment/Information Request	Nonclinical	
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Date Range: All
Date Communication Type Document Type Document Subtype Serial / Supp #

"NDA 21-319; Dutasteride Soft-Gelatin Capsules
Comment/Information Request: Nonclinical

07-Aug-2001 GlaxoSmithKline Correspondence Response to FDA Request/Comment Nonclinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment: Nonclinical

14-Aug-2001 GlaxoSmithKline Correspondence Response to FDA Request/Comment Statistical

NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment: Statistical

20-Aug-2001 Food and Drug Administration Correspondence Comment/Information Request CMC

NDA 21-319; Dutasteride Soft-Gelatin Capsules
Comment/Information Request: CMC

23-Aug-2001 GlaxoSmithKline Correspondence Response to FDA Request/Comment Clinical Efficacy

NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment

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Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

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Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
04-Sep-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Nonclinical	Response to FDA Request/Comment	Nonclinical	
06-Sep-2001	GlaxoSmithKline Telephone Conversation NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Statistical	Response to FDA Request/Comment	Statistical	
07-Sep-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: Clinical, Statistical	General Correspondence	Clinical Statistical	
07-Sep-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: CMC - August 27, 2001	Response to FDA Request/Comment	CMC	
10-Sep-2001	Food and Drug Administration Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules	User Fee Invoice	Product	

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Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

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Date	Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
	All				
	User Fee Invoice				

13-Sep-2001	GlaxoSmithKline Telephone Conversation	Response to FDA Request/Comment	Clinical Statistical
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment: Clinical, Statistical

19-Sep-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Clinical Statistical
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment: Clinical, Statistical

25-Sep-2001	GlaxoSmithKline Telephone Conversation	General Teleconference	CMC
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
General Teleconference: CMC

26-Sep-2001	GlaxoSmithKline Telephone Conversation	General Teleconference	CMC
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
General Teleconference: CMC

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Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

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27-Sep-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC	General Correspondence	CMC	
01-Oct-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: CMC	Response to FDA Request/Comment	CMC	
04-Oct-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC	General Correspondence	CMC	
04-Oct-2001	Food and Drug Administration Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request: Clinical	Comment/Information Request	Clinical	
09-Oct-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Amendment to Pending Application: CMC	Amendment to Pending Application	CMC	

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Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
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09-Oct-2001	Food and Drug Administration Telephone Conversation	General Teleconference	Meeting Agenda or Details Meeting Request	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
General Teleconference: Meeting Request

09-Oct-2001	Food and Drug Administration Correspondence	Minutes of Meeting Comment/Information Request	FDA Conference CMC	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Minutes of September 25 CMC Meeting

10-Oct-2001	Food and Drug Administration Correspondence	Minutes of Meeting	FDA Conference	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Minutes of Meeting: FDA Conference

11-Oct-2001	GlaxoSmithKline Correspondence	Amendment to Pending Application	CMC	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Amendment to Pending Application: CMC

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30-Nov-2001
Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
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11-Oct-2001	GlaxoSmithKline Correspondence	General Correspondence	CMC Field Copy	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
General Correspondence: CMC Field Copy

11-Oct-2001	GlaxoSmithKline Telephone Conversation	General Teleconference	Clinical Nonclinical Safety	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
General Teleconference: Clinical, Nonclinical, Safety

15-Oct-2001	GlaxoSmithKline Correspondence	General Correspondence	Labeling Other	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
General Correspondence: Other, Trade Name

15-Oct-2001	GlaxoSmithKline Telephone Conversation	Response to FDA Request/Comment	Advisory Committee Meeting	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment
Clinical Pharmacology and Biopharmaceutics Review Letter

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30-Nov-2001

Application:

NDA 21319; Dutasteride Soft-Gelatin Capsules

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Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
17-Oct-2001	Food and Drug Administration Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Minutes of Meeting: FDA Conference	Minutes of Meeting	FDA Conference	
18-Oct-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules NDA 20-241: LAMICTAL® (lamotrigine) Tablets General Correspondence: Request for a User Fee Refund Check	General Correspondence	Other	
24-Oct-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: CMC	Response to FDA Request/Comment	CMC	
24-Oct-2001	Food and Drug Administration Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request: Labeling	Comment/Information Request	Labeling	
31-Oct-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	BA/BE Clinical	

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Date Range: All Date Communication Type Document Type Document Subtype Serial / Supp #

NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment

02-Nov-2001 GlaxoSmithKline FAX/E-mail Response to FDA Request/Comment Labeling

NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment: Labeling

05-Nov-2001 GlaxoSmithKline Correspondence Response to FDA Request/Comment Labeling

NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment: Labeling

07-Nov-2001 Food and Drug Administration Correspondence User Fee Invoice
Comment/Information Request

NDA 21-319; Dutasteride Soft-Gelatin Capsules
NDA 20-241; LAMICTAL® (lamotrigine) Tablet
Re: GlaxoSmithKline, Request for Refund of Application Fees
User fee ID #4203 and #4204

JLP41868

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30-Nov-2001

Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Regulatory Affairs
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Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
08-Nov-2001		GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Labeling	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Labeling			
08-Nov-2001		Food and Drug Administration FAX/E-mail	Comment/Information Request	Labeling	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request: Labeling			
08-Nov-2001		GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Labeling	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Labeling, Packaging			
13-Nov-2001		Food and Drug Administration FAX/E-mail	Comment/Information Request	Labeling	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request: Labeling			
15-Nov-2001		GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Nonclinical	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Nonclinical; Phase 4 Commitment			

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**Regulatory Affairs
CARDS**

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Chronology

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30-Nov-2001 Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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16-Nov-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Labeling	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment: Labeling

16-Nov-2001	Food and Drug Administration FAX/E-mail	Comment/Information Request	Labeling	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Comment/Information Request: Labeling

19-Nov-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Labeling	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment: Labeling

20-Nov-2001	Food and Drug Administration Correspondence	Approval Letter	Labeling	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules
Approval Letter

30-Nov-2001	GlaxoSmithKline Correspondence	General Correspondence		
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General Correspondence: Other
Notification of Corporation Name Change - Reproductive and Urologic

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30-Nov-2001

Application: NDA

21319; Dusteride Soft-Gelatin Capsules

Chronology

12:17:58

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Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
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